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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,023	03/07/2001	Barbro Hemmendorff	10806-155	3513

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[REDACTED] EXAMINER

CHUNDURU, SURYAPRABHA

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

I637

DATE MAILED: 09/24/2002

(L)

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/743,023	HEMMENDORFF ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 July 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-3,5-8 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5-8 and 11-22 is/are rejected.
- 7) Claim(s) 20 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .  | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

1. Applicants' response to the office action and amendment (Paper No. 11) filed on July 2, 2002 has been entered.
2. The disclosure is objected because of the following informalities:

Claim 20 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Response to Arguments***

3. Applicant's response to the office action (Paper No.11) is fully considered and deemed persuasive in part.
4. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.11).
5. The following is the rejection made in the previous office action under 35 U.S.C. 102(e):

Claims 1-3, 5-8, 11-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Builder et al. (USPN. 5,663,304).

Builder et al. teach a method for production of recombinant peptides comprising fermenting cells (host cells) to produce recombinant peptides in the presence of metal salt (alkali metal salt) prior to peptide isolation (see column 26, lines 34-67, column 27, 1-67, column 28, lines 15-33, column 6, lines 42-67, and column 7, lines 1-9). Builder also teach that (i) the use of metals facilitate disulfide oxidation of polypeptides and yield correct refolding of a misfolded polypeptide contained in host cells (see column 6, lines 42-60); metal salts include sodium

Art Unit: 1637

chloride, potassium chloride, sodium phosphate, potassium phosphate (see column 28, lines 15-33, column 11, lines 42-54); alkali metal salt buffer (pH 10.5) was added after fermentation and pH was adjusted to 3.5 with phosphoric acid (see column 28, lines 28-33 and column 16, lines 47-55); recombinant polypeptides of interest include human growth factor (see column 8, lines 24-67, and column 9, lines 1-10). Thus, the disclosure of Builder et al. meets the limitations in the instant claims.

**Response to Arguments:**

Applicant's arguments with respect to the rejection made under 35 U.S.C. 102(e) have been considered and are found not persuasive. Applicants argue that the method comprises fermenting cells to produce the recombinant peptides by adding metal salt during or after the fermentation step, prior to peptide isolation, which is disclosed in the prior art of record. The instant method comprises the similar steps as disclosed in the prior art of the record. Applicants argue that the instant invention is drawn to the method for the production of recombinant peptides with low amounts of trisulfides. The limitation 'the low amount of trisulfides' on which applicants relay, does not specify how low the trisulfides are, i.e. the specific value(s) of trisulphides is not recited in the claims. Further,

As MPEP 2111.02 notes, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." This limitation in the preamble of the claim is not given patentable weight.

Applicants' particular argument that the IGF-I is not known to produce trisulfides is fully considered and Applicants correctly pointed it out. However, Builder et al. also teaches the use of the method not only in the production of IGF-I, but also in the production of other polypeptides (such as growth hormone, relaxin chains, urokinase, immunotoxins). Further, the prior art of the record uses a special buffer which avoids the necessity of using more expensive disulfide-exchange agents such as glutathione and also avoids the possibility of producing polypeptide containing disulfide adducts which favor for refolding of misfolded polypeptide (see column 7, lines 10-21). Hence the method as disclosed in the prior art of the record inherently teaches the low amounts of trisulfides. Therefore, the prior art of the record teach meets each of the limitations found in the claims. Further, the claim is of the open "comprising" format, which permits the inclusion of additional elements, so that any additional steps are permitted in the claim. Therefore the rejection is maintained herein.

New claims 21 and 22 are herein, rejected under the prior art of the record (Builder et al., USPN. 5,663,304) as Builder et al. teach the method as discussed in the above rejection. Further Builder et al. teach that the polypeptides produced by the method include growth hormone (see column 9, lines 11-21); and pH during or after fermentation was less than or equal to 7 (see column 28, lines 5-33).

### *Conclusion*

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1637

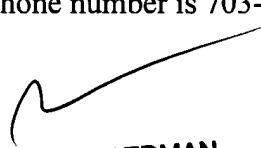
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru  
September 19, 2002

  
JEFFREY FREDMAN  
PRIMARY EXAMINER